K122267

OCT 2 2012

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	July 26, 2012
Submitter:	Ohmeda Medical, a Division of Datex-Ohmeda, Inc., A General Electric Company 8880 Gorman Rd. Laurel, MD 20723
Primary Contact Person:	Agata Anthony 8880 Gorman Rd. Laurel, MD 20723 Tel: 410-456-0329 Fax: 410 888 0544
Secondary Contact Person:	Kenny M Bello 8880 Gorman Rd. Laurel, MD 20723 Tel: 410-888-5393 Fax: 410 888 0544
Device: Trade Name:	Giraffe and Panda Warmers
Common/Usual Name:	Infant Warmer
Classification Names:	Warmer, Infant Radiant
Product Code:	FMT 880.5130
Predicate Device(s):	Giraffe and Panda Warmers; K101804
Device Description:	The Giraffe and Panda Warmers are devices with a radiant heating source intended to maintain the thermal balance of an infant patient by direct radiation of energy in the infrared region of the electromagnetic spectrum. The warmers operate similarly to warmers currently in use in hospitals. Radiant heat from an infrared heat source is focused onto the bed to warm the patient. The operator may select either the heater power or skin temperature control method. Depending on the control method selected, the heater is either regulated at the operator selected power level or the heater output is modulated to maintain the patient's temperature at the value selected by the operator. Infant radiant warmers are also used to provide thermal support during surgical procedures and during procedures such as extracorporeal membrane oxygenation, resuscitation, or other procedures requiring open access and thermal support. Both units also feature

optional integrated SpO2 and Resuscitation modules. The Resuscitation Module may feature either a traditional bag-and-mask technology or a T-piece technology. Both the SpO2 module and the Resuscitation Modules use existing technology. The Giraffe and Panda Warmers can be used with the Giraffe Shuttle and a UPS module, a mobile power source that allows for transport of the patient between care areas within the hospital building and provides power to the Warmers.

Description of Device Modification

The proposed modification of the Giraffe and Panda Warmers is the addition of the Nellcor pulse oximetry to the legally marketed Giraffe and Panda Warmer system. The integrated SpO2 features are substantially equivalent to the corresponding parameters in the Masimo SET technology. The indication for use of the legally marketed device will remain unchanged with the addition of this optional pulse oximetry system.

Indication for Use: Infant radiant warmers provide infrared heat in a controlled manner to neonates who are unable to thermo-regulate based on their own physiology. Infant radiant warmers may be used to facilitate the neonate's transition to the external environment or to provide a controlled open environment. An optional integrated SpO2 monitoring feature may be used for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (Sp02) and pulse rate (measured by a SpO2 sensor). An optional integrated resuscitation system may be used to provide the basic equipment required for pulmonary resuscitation of infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures and/or manual ventilation to the infant.

Device Modification Technology:

Nellcor Pulse Oximetry is an optional technology for Giraffe and Panda Warmers, and provides continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by a SpO2 sensor) non-invasively via a light signal, which is fundamentally equivalent to Masimo Pulse Oximetry.

The technique used to integrate the Nellcor SpO2 option into the Giraffe and Panda Warmers is extremely similar to the technique used to integrate the current Masimo SpO2 option. This technique provides supplemental electrical isolation of the SpO2 option electronics and patient connection from the rest of the Giraffe and Panda Warmers. Connection of the Nellcor SpO2 option to the Giraffe and Panda Warmers is accomplished through the same cable as used for the Masimo SpO2 option. This cable provides electrical power, ground and RS-232 communications signals. These signals are carried over the isolation barrier using components providing supplemental electrical isolation.

The Nellcor SpO2 option uses the same module technology as in the predicate device (K101804). The data generated by the module is transferred to the Giraffe and Panda Warmers over the RS-232 serial signals, and contains the pulse rate, saturation and alarm information. The Giraffe and Panda Warmers display this information without change in meaning.

The proposed modification does not change the indication for use of the legally marketed product (K101804).

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Giraffe and Panda Warmers and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, Giraffe and Panda Warmers, used with Nellcor Pulse Oximetry did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Giraffe and Panda Warmers, used with Nellcor Pulse Oximetry to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 2 2012

Ohmeda Medical, a Division of Datex-Ohmeda, Incorporated,
A General Electric Company
Agata Anthony
Regulatory Affairs Director
8880 Gorman Road
Laurel, Maryland, 20723

Re: K122267
Trade/Device Name: Giraffe and Panda Warmers
Regulation Number: 21 CFR 880.5130
Regulation Name: Infant Radiant Warmer
Regulatory Class: II
Product Code: FMT
Dated: September 4, 2012
Received: September 6, 2012

Dear Ms. Anthony:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

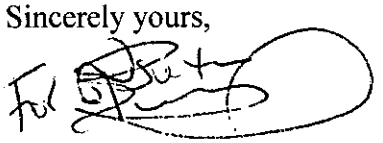
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Giraffe and Panda Warmers

Indications for Use:

Infant radiant warmers provide infrared heat in a controlled manner to neonates who are unable to thermo-regulate based on their own physiology. Infant radiant warmers may be used to facilitate the neonate's transition to the external environment or to provide a controlled open environment. An optional integrated SpO2 monitoring feature may be used for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (Sp02) and pulse rate (measured by a SpO2 sensor). An optional integrated resuscitation system may be used to provide the basic equipment required for pulmonary resuscitation of infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures and/or manual ventilation to the infant.

Prescription Use_X___ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

10/1/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122267